EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EU) No 37/2010 as regards the classification of the substance rafoxanide with respect to its maximum residue limit in foodstuffs of animal origin

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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amending Regulation (EU) No 37/2010 as regards the classification of the substance rafoxanide with respect to its maximum residue limit in foodstuffs of animal origin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council[1], and in particular Article 14, in conjunction with Article 17 thereof,

Whereas:

(1) In accordance with Regulation (EC) No 470/2009, the Commission is to establish, by way of a Regulation, maximum residue limits ('MRLs') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010[2] sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Rafoxanide is already included in that table as an allowed substance for bovine and ovine species, applicable to muscle, fat, liver and kidney. The provisional MRL for that substance set out for bovine and ovine, applicable to milk, expired on 31 December 2017.

(4) In accordance with Article 27(2) of Regulation (EC) No 470/2009, on 21 February 2023, Ireland submitted a request to the European Medicines Agency ('Agency') for the extrapolation of the existing entry for rafoxanide to bovine and ovine milk.

(5) On 20 April 2023, through the opinion of the Committee for Veterinary Medicinal Products, the Agency recommended the establishment of a definitive MRL for rafoxanide in bovine and ovine milk.

(6) In accordance with Article 5 of Regulation (EC) No 470/2009, the Agency is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs

[1] OJ L 152, 16.6.2009, p. 11.

[2] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

established for a pharmacologically active substance in one or more species for other species.

(7) The Agency concluded that the extrapolation of the existing entry for rafoxanide to all ruminants, except ovine, is appropriate.

(8) In view of the opinion of the Agency, the Commission considers it appropriate to establish an MRL for rafoxanide in bovine and ovine, in relation to milk and to extrapolate the MRL for rafoxanide to all ruminants except ovine.

(9) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN